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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/932,821	08/17/2001	Katherine D. Gordon	1540/140	4514

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EXAMINER
BAHAR, MOJDEH

ART UNIT	PAPER NUMBER
1617	7

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/932,821	GORDON ET AL.	
	Examiner	Art Unit	
	Mojdeh Bahar	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *1-3 (in part), 4, 7-8 (in part),9,10 and 12-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3(in part),5-6, 7-8 (in part),11 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The applicant's response to the restriction requirement 0f 12/05/01 is acknowledged. Applicant's election with traverse of the invention of Group IV and the disorder specie, Epileptic seizure, in Paper No. 7 submitted January 28, 2002 is acknowledged. The applicant has stated that the restriction requirement was not clear. Applicant has also referenced a phone conversation with SPE Minna Moezie during which the SPE has clarified the restriction requirement by stating that there are 4 groups, a method of treatment employing an estrogenic lipophilic compound, a method of treatment employing a non-estrogenic lipophilic compound, a dosage unit comprising an estrogenic lipophilic compound, and a dosage unit comprising a non-estrogenic lipophilic. **The modified restriction requirement is as follows:**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 (in part), 4, 7-11 (in part), drawn to a method of treating acute medical condition in a subject comprising administering an estrogenic lipophilic agent in an oil formulation in the presence of benzyl alcohol, classified in class 514, subclass to be determined.

II. Claims 12-15, 16-18 (in part), 20-21 drawn to a dosage unit composition comprising a formulation of a non-estrogenic lipophilic molecule in an oil packaged in a dosage unit, classified in class 514, subclass to be determined. *Claim 19 does not further limit the base claim 12.

III. Claims 16-18(in part) and 19* drawn to a dosage unit composition comprising a formulation comprising an estrogenic compound, classified in class 514, subclass

221. Note that claim 19 is drawn to an estrogenic lipophilic molecule, but they are dependent from a claim drawn to a non-estrogenic compound.

IV. Claims 1-3 (in part), 5-6, 7-11 (in part) and 22-25, drawn to a method of treating an acute medical condition in a subject comprising administering to the subject a non-estrogenic lipophilic agent in an oil formulation, classified in class 514, subclass to be determined.

Inventions I and II as well as III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant an estrogenic compound can be used in the treatment of a menopausal woman in hormone replacement therapy (non-acute/chronic condition). Diltiazim hydrochloride, a hydrophilic molecule is used in treating myocardial infarction.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation because they employ different agents. Similarly inventions I and IV are unrelated because they too have different modes of operation.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Specie election

Claims 1-25 are generic to a plurality of disclosed patentably distinct species comprising different acute medical conditions. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. The treatment of each acute medical condition i.e., vasospasm, head injury, myocardial infarction represents a separate field of medical technology having a separate field of search. For example vasospasm is routinely treated with calcium channel blockers, whereas head injury can be treated by employing analgesics. The search for treatment of all acute medical conditions is therefore an undue burden on the office. Note that the search is not limited to patent files.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species**, one specific disorder/disease,** even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The traversal is on the ground(s) that section 808.01 of the MPEP states that the standard for independent claims is that there be "no disclosed relationship therebetween". Note that Groups I,II and III,IV are related invention and the restriction among them is based on section 806.05 (h) related inventions and not on 808.01.

Applicant's comments regarding the lipophilic nature of Nitroglycerin are persuasive and a different (i.e., hydrophilic agent) has been used to demonstrate that a materially different product can be used in treating myocardial infarction and/or angina in a subject.

Applicant further states that the different modes of operation of Groups I and IV is not clear. Note that Group I is drawn to a method of treating acute medical condition in a subject comprising administering **an estrogenic lipophilic agent,** while Group IV is drawn to a method of treating acute medical condition in a subject comprising administering **a non-estrogenic lipophilic agent.** The employment of two different agents, estrogenic versus non-estrogenic constitutes different modes of operation. Similarly, Group II is drawn to a dosage unit composition comprising a formulation of a **non-estrogenic lipophilic molecule**, whereas Group III is drawn to a dosage unit composition comprising a formulation of **an estrogenic lipophilic molecule.** The employment of two different agents, estrogenic versus non-estrogenic constitutes different modes of operation.

The requirement is still deemed proper and is therefore made FINAL.

Claims 4, and 12-21 are withdrawn from consideration since they are drawn to non-elected inventions. Claims 1-3 and 7-11 (all in part) in so far as they read on an estrogenic lipophilic agent have been withdrawn as since they are drawn to non-elected invention.

Claims 9-10 are withdrawn from consideration since they are drawn to non-elected species.

Claims 1-3 (in part), 5-6, 7-8 (in part), 11 and 22-25 are herein examined on the merits in so far as they read on the elected specie.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3 (in part), 5-6, 7-8 (in part), 11 and 22-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Bechgaard et al. (USPN 5,397,771).

Bechgaard et al. (USPN 5,397,771) teaches a method of administering a composition comprising benzodiazepines, and more specifically diazepam (an anti-epileptic compound), vegetable oil (i.e., soybean oil, peanut oil, corn oil, olive oil, sunflower oil, castor oil), see specifically col. 4, lines 30-32, col. 10, lines 64-67 and claims 1, 12 and 13. Bechgaard et al. (USPN 5,397,771) also teaches that its pharmaceutical composition may also include alcohols, such as benzyl alcohol, see specifically Table 7 as well as col. 10, lines 50-63. Bechgaard et al. (USPN 5,397,771) further teaches that its vehicle system increases the possibility for designing a controlled release formulation such as diazepam formulation which avoids peak plasma concentrations, see col. 10, lines 42-49, see also Tables 1-5 which show that the peak plasma concentrations after administration of benzodiazepines is reaches in less than 4 hours.

Bechgaard teaches intranasal and intravenous administration of its composition, see abstract and example 7. Bechgaard also teaches that the delivery system can be optimized, see particularly col. 10, lines 21-23.

Bechgaard et al. (USPN 5,397,771) does not particularly teach subcutaneous administration of its diazepam composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the administer the composition of Bechgaard intravenously.

One of ordinary skill in the art would have been motivated to administer the composition of Bechgaard intravenously because intraconversion of dosage forms and routes of administration are within the skill of the artisan and are therefore obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
February 22, 2002

MINNA MOEZIE, J.D.
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